

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Registration Number: 3125-339; PRYFON 6  
Emulsifiable Insecticide. Action code: 305.  
Record No.: 224366.

From: Van M. Seabaugh *bms 4-6-89 E 4/7/89*  
Precautionary Review Section  
Registration Support Branch  
Registration Division (H75-05C)

To: William Miller (PM 17)  
Insecticide/Rodenticide Br.  
Registration Division (H75-05C)

Applicant: Mobay Corporation  
Agricultural Chemicals Division  
P.O. Box 4913  
Kansas City, Missouri 64120

Formulation From Label (1-8-87)

|  |                 |
|--|-----------------|
| <u>Active Ingredient:</u>  | <u>% by wt.</u> |
| 1-Methylethyl 2-[[ethoxy[(1-,methylethyl)<br>amino]phosphinothioyl]oxy]benzoate..... | 65.0            |
| <u>Inert Ingredients:</u> .....  | 35.0            |
|  | 100.0           |

Summary

We are responding to the application for amendment (EPA Form 8570-1; 2-19-88; from John Thornton to William Miller). The registrant proposed revised labeling, and requested that Child Resistant Packaging be used in lieu of Restricted Use classification.

This product meets the criteria for restricted use (40 CFR §162.10), and must remain classified for restricted use. In this case, the intent for the criteria of 40 CFR §162.10 was not to allow a termiticide product with Restricted Use classification to have this requirement dropped because of a change to Child Resistant Packaging (CRP). The submitted revised label (2-5-88 Draft) is not acceptable, and must have the labeling for a Restricted Use Pesticide. At this time, the Agency is not requiring CRP (40 CFR, Part 157) for this product.

The Registrant proposes different instructions for the label as follows: "Change re-treatment with syrup of ipecac from 10 to 20 minutes to 5 to 10 minutes. It is now the consensus that 20 minutes is too long a period to wait if vomiting does not occur."

This part of the label as proposed by the registrant is stated as follows:

Statement Of Practical Treatment

If Swallowed: Call a physician or Poison Control Center. If medical assistance cannot be given immediately, induce vomiting and get to a hospital.

To induce vomiting, administer 1 or two glasses of water and stick finger down throat. Repeat until vomitus is clear. Or, if available, administer syrup of ipecac (1/2 oz. or 15 ml). If vomiting does not occur within 5 to 10 minutes, administer a second dose of ipecac.

Do not attempt to give anything by mouth or induce vomiting in an unconscious or convulsing person.

The proposed label change regarding induction of emesis is not acceptable. No data have been submitted to support this change. The Precautionary Review Section will not agree to this change without substantial scientific support. Reducing the interval between doses of syrup of ipecac has the potential for overdosing with ipecac, and is contrary to use directions for ipecac. Other EPA staff remarks for this part of the label are as follows:

1. Both instructions, "within 10 to 20 minutes" and "within 5 to 10 minutes" are confusing. What do we expect the rescuer to do? Under the present label, when 10 minutes is up, does he/she wait for 15 or draw a random number between 10 and 20?
2. Recognition And Management Of Pesticide Poisonings by Donald P. Morgan, M.D., Ph.D. (EPA 540/9-80-005; p. 7). This statement and others in the book should be taken into consideration.

"If pesticide has been ingested in quantity sufficient to cause poisoning, empty the stomach and intestine.

If victim is alert and respiration is not depressed, give syrup of ipecac, followed by 1-2 glasses of water to induce vomiting. Adults (12 years and over): 30 ml; children under 12 years: 15 ml.

Caution: Observe victim closely after administering ipecac. If consciousness level declines, or if vomiting has not occurred in 15 minutes, proceed immediately to intubate the stomach.

Following emesis, have victim drink a suspension of 30-50 gm activated charcoal in 3-4 ounces of water to limit absorption of toxicant remaining in the gut."

3. A discussion with Roxane Laboratoires (a manufacturer of syrup of ipecac) indicated that current labeling directs the user to delay administration of a second dose for 30 minutes for children and 20 minutes for adults. It was Roxane's belief that shortening the dose administration cycles decreases the exposure time necessary for effectiveness and may in fact lead to overdosing. The label also advises the user to call a physician or Poison Control Center prior to use.

4. "Brief Clinical And Laboratory Observations"  
I.A. Dabbous, M.D., A.B. Bergman, M.D., and  
W.O. Robertson, M.D. (J. Of Pediatrics, 1965)

"...The average interval between administration of syrup of ipecac and resultant emesis was 17 minutes..."

5. Agency's Recommended Statements Of Practical Treatment Of Emesis

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

or

IF SWALLOWED: Call a Physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or, if available, by administering syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconscious person.